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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KAHELIN, MICHAEL WILLIAM	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/801,139	HAEFNER, PAUL	
	Examiner	Art Unit	
	Michael Kahelin	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The amendment to the abstract is acknowledged and accepted. The objection is withdrawn.

Claim Rejections - 35 USC § 112

2. The amendments to claims 7,11,16, and 22-24 in regards to the rejections under 112(2) are acknowledged and accepted. The 112(2) rejections are withdrawn.

Response to Arguments

3. Applicant's arguments filed 1/17/2006 have been fully considered but they are not persuasive. In regards to independent claims 1, 32, and 44, Applicant argued that Schaldach (US 4,867,163) fails to anticipate the claims because Schaldach measures stroke volume using a pressure sensor or microphone, which would not produce audio, and is thusly not an audio signal. Furthermore, Applicant cites the New Oxford American Dictionary and the American Heritage Dictionary as evidence that "audio" is defined as and limited to "sound". Applicant is reminded that claim language is to be interpreted in its "broadest reasonable interpretation", and the edition of the American Heritage Dictionary that Examiner consulted included a definition of audio as: "of or relating to the broadcasting, reception, or reproduction of sound". Therefore, irrespective of whether the signal measured by Schaldach's invention produces a sound

perceivable by the human ear, it is still an "audio signal" because it is an electrical analog (acquired by a microphone) of the sound produced in the heart.

4. In regards to claims 2 and 35, Applicant argued that "an indication of patient activity, not the accelerometer signal itself, is used in connection with the 'characteristic field'" and that there is no teaching that the characteristic field comprises the acceleration signal. As shown in Figure 5, element 520 and column 20, lines 37-46, the signals output from 515 and 520 are "redundant and can be put in relation to one another in the subsequent characteristic field in order to increase the reliability". Also, column 20, line 34 clearly states that acceleration is measured (inherently by an accelerometer), thusly meeting the claim language.

5. In regards to claims 30 and 38, Applicant argued that the signals are not time-correlated, but only concurrently displayed or superimposed. Examiner pointed to column 23, line 46 as evidence of anticipation of "providing a time correlation" by "superimposing two characteristic fields". This step of "superimposing two characteristic fields" is further explained above; starting at column 23, line 20, where Schaldach discloses "standardize[ing] the triggering". A skilled artisan will recognize this as periodically acquiring data, which in this case are two superimposed characteristic fields (i.e. audio signal and electrical signal). Standardized triggering of two superimposed characteristic fields is "time correlation" because the relationship between the two variables is acquired and compared over time.

6. In regards to claim 17, Applicant argued that Shaldach's output is not an "audio output" because "audio" is defined as "sound", which is supported by the language of

claim 18; and that providing an output capable of being heard by the human ear is not well-known in the art and would not have a reasonable expectation of success to be combined with Schaldach's invention because a speaker only produces sound when driven with an audio signal. In response to the argument that "audio" is defined only as "sound", Applicant is directed to paragraph 3 above. The term "audio" can reasonably be interpreted as an electrical or visual manifestation of the mechanical vibrations that are "sound". If "audio" is defined only as "sound" it would be very difficult to imagine how Applicant's "audio signal" is sensed and stored without representing the signal in alternative manifestations, such as electrical signals. In response to the argument that claim 18 differentiates the visual output of claim 18 from the audio output of claim 17, Examiner is interpreting claim 18 as further limiting the "audio output" (i.e. output representative of the audio information acquired in the heart) by displaying it in a visual format, instead of several other possible output modalities. In response to the argument that providing an output capable of being heard by the human ear is not well-known in the art and would not have a reasonable expectation of success to be combined with Schaldach's invention because a speaker only produces sound when driven with an audio signal, Applicant is directed to US 5,010,899; US 5,737,429; US 4,220,160; and US 4,362,164, among many others, that teach of providing audio data from the heart to a clinician to diagnose heart abnormalities by ear. In response to the lacking expectation of success, the claim mentions nothing of a speaker. The prior art was relied on only for the teaching of providing audio data from the heart to a clinician to diagnose heart abnormalities by ear, such as taught by Kimball in US 4,220,160.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 5-7, 9, 10, 12, 13, 16, 25, 30, 32, 35, 37-39, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Schaldach (4,867,163).

9. In regards to claims 1, 32 and 44, Schaldach discloses an implantable housing (160) containing a plurality of electrodes (col. 8, lines 1 and 25), detection circuitry (111), a sensor to detect movement of the heart and produce an audio signal (117-120 and col. 7, line 61), a memory (112) to store the signals, a controller (113), and communications circuitry to telemeter the electrical and audio signals (125) to an external device (150).

10. In regards to claims 2 and 35, Schaldach discloses a device using an accelerometer (col. 20, line 31 and claim 10). Please note that the "characteristic field" signal comprises the acceleration signal.

11. In regards to claims 3, 5 and 37, the sensor comprises a pressure transducer or a microphone (col. 20, line 67).

12. In regards to claims 6 and 10, the sensor and/or electrode is located on the housing (col. 9, line 21).

13. In regards to claim 7, the sensor is located on a lead (col. 9, line 20).

14. In regards to claims 9 and 39, at least one of the electrodes is configured for intrathoracic placement (col. 8, line 25).

15. In regards to claims 12 and 13, the device further comprises energy delivery circuitry, specifically pacing therapy (col. 7, line 13).

16. In regards to claims 16 and 25, the patient external device comprises a storage media to store the signals (159 and 153).

17. In regards to claims 30 and 38, the two signals are time correlated and is indicated by their concurrent display on the monitor (col. 23, line 46).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 17, 19-21, 41, 45 and 46 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schaldach. Schaldach discloses that the user interface (150) provides a visual graphical output representative of the cardiac electrical signal (col. 23, line 20) and an audio output representative of the audio signal. Please note that the examiner is interpreting any manifestation of an audio signal as an audio output. Thus, although the output is displayed visually, it is still an audio output. In the alternative, it is well known in the art to provide audio signals representative of the audio events of the heart, for example by

stethoscope or speaker, so that cardiac maladies can be quickly diagnosed by ear. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an audio output to Schaldach's invention to provide a means to quickly diagnose cardiac maladies by ear.

20. Claims 4 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaldach in view of Turcott (6,477,406). Schaldach discloses the essential features of the claimed invention except for a piezoelectric transducer. Turcott teaches of using a piezoelectric transducer with an implantable housing (col. 10, line 17) to provide an inexpensive mechanical-to-electrical transducer that is sensitive to a frequency band within the limits of human hearing and human heart sounds. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a piezoelectric transducer with an implantable housing to provide an inexpensive mechanical-to-electrical transducer that is sensitive to a frequency band within the limits of human hearing and human heart sounds.

21. Claims 8, 11, and 40 rejected under 35 U.S.C. 103(a) as being unpatentable over Schaldach in view of Kadhiresan (5,935,081). Schaldach discloses the essential features of the claimed invention except for subcutaneous, non-intrathoracic placement of the sensor/lead. Kadhiresan teaches of an implantable device with a heart motion detector, which is implanted subcutaneously and in a non-intrathroacic location (col. 2, line 59) to simplify the implantation and a lead to connect the electrodes to the housing (col. 3, line 2). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an implantable device with a heart

motion detector, which is implanted subcutaneously and in a non-intrathroacic location to simplify the implantation and a lead to connect the electrodes to the housing.

22. Claims 14, 18, 22-24, 31, 33, 34, 43, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaldach in view of Gessman (5,321,618). Schaldach discloses the essential features of the claimed invention except for providing defibrillation therapy, providing an audio output for the cardiac electrical signal, providing a speaker, telemetering in response to a user request, telemetering in response to a patient-external device request, and telemetering in real-time. Gessman teaches of an implantable cardiac device that provides defibrillation therapy to treat a variety of arrhythmias, provides an audio output in the form of a speaker for outputting the cardiac electrical signal to transfer the signal information in a way that is perceivable to humans, telemetering in response to a user request and a patient external device request (col. 4, line 57) to allow transmission at a time that is convenient for the user, and telemetering in real-time to provide immediate information on the state of the patient. Therefore, it would have been obvious to someone having ordinary skill in the art at the time the invention was made to modify Schaldach's invention by providing defibrillation therapy to treat a variety of arrhythmias, providing an audio output in the form of a speaker for outputting the cardiac electrical signal to transfer the signal information in a way that is perceivable to humans, telemetering in response to a user request and a patient external device request to allow transmission at a time that is convenient for the user, and telemetering in real-time to provide immediate information on the state of the patient. Please note that the examiner is interpreting the

electromagnet device (26) as the patient external device that requests transmission. Since the patient applies this element to the proximity of the implant, it is also user-requested. Also, Gessman's teaching inherently transmits in real-time because the apparatus is lacking a memory (Fig. 1).

23. Claims 15, 26-29, 42, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaldach in view of Riff et al. (2002/0026223 A1). Schaldach discloses the essential features of the claimed invention except for storing signals based on a patient-actuatable trigger, a server coupled to the patient-implantable device and the patient external device, telemetering from the patient-implantable device to the server to the patient-external device, and telemetering from the patient-implantable device to the patient external device to the server. Riff et al. teach of an implantable device system which stores signals based on a patient-actuatable trigger (par. 0026) to provide cardiac information whenever the patient desires, a server in communication with the implantable and external device (113) to store large amounts of patient data that is accessible to many people, telemeters from the patient-implantable device to the server (102 to 112) to the patient-external device (112 to 118) to update the server and provide accurate server information to the external device, and telemeters from the patient-implantable device (102 to 104) to the patient external device to the server (104 to 112) to provide the patient with the data before it is sent to the server. Therefore, it would have been obvious to someone having ordinary skill in the art at the time the invention was made to provide Schaldach's invention with a system which stores signals based on a patient-actuatable trigger to provide cardiac information whenever

the patient desires, a server in communication with the implantable and external device to store large amounts of patient data that is accessible to many people, telemeters from the patient-implantable device to the server to the patient-external device to update the server and provide accurate server information to the external device, and telemeters from the patient-implantable device to the patient external device to the server to provide the patient with the data before it is sent to the server.

Conclusion

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GEORGE R. EVANISKO
PRIMARY EXAMINER
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